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(54) **Container for disposable needle**

(57) The present invention relates to a container for a disposable needle, intended to facilitate needle placement for the infusion of a liquid drug under a patient's skin, the container comprising: a cylindrical housing (1; 101) in which there are defined a cap (1a; 101a) and a sleeve (1b; 101b) provided with a resting base (1c; 101c), said cap (1a; 101a) being axially slidable relative to said sleeve (1b; 101b) when a sufficient pressure is exerted on said cap (1a; 101a); a needle (21; 121),

which is located inside said housing so as to be directed towards said resting base (1c; 101c) and is equipped with a cannula (11; 111) coming out of said housing (1; 101) for the infusion of the drug through said needle (21; 121); a retaining member (9; 109), which is located within said housing (1; 101) between said cap (1a; 101a) and said sleeve (1b; 101b) and to which said needle (21; 121) is secured; said container being equipped with means for releasing said needle (21; 121) when said cap (1a; 101a) is made to slide on said sleeve (1b; 101b).

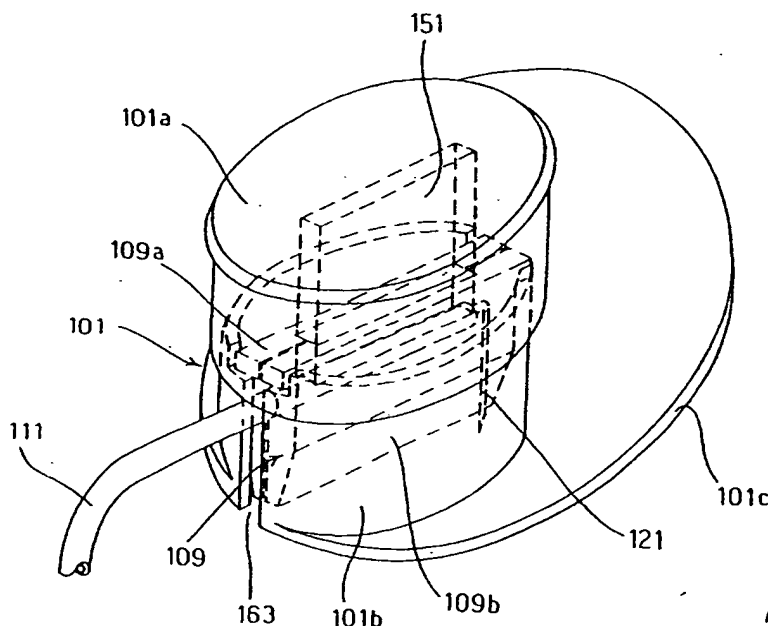


FIG. 7

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Description

[0001] The present invention relates to a container for a disposable needle. More particularly, the invention refers to a container for a disposable needle for drug infusion, which container makes needle placement through a patient's skin easier.

[0002] As known, several medical treatments exploit subcutaneous infusion of liquid drugs: the drug flows through a cannula connected to a needle placed through the patient's skin and it is directly delivered under the skin. In some cases, the patient himself/herself is to administer the drug. For instance, many diabetic patients self-administer insulin, in the form of controlled and prolonged infusion.

[0003] Clearly, many patients have no medical knowledge and therefore they may be reluctant to place the needle through their skin or inexperienced in doing so. Thus, it is necessary to provide means allowing automatic needle placement, so as to prevent the patient's lack of skill or hesitation from resulting in an incorrect needle placement, with possible dangerous consequences.

[0004] Devices of this kind already exist and one of them is disclosed in patent application WO 98/33549.

[0005] According to the teaching of the above mentioned patent application, a device for needle placement comprises a cylinder, the lower portion of which can receive the outward-directed needle and related cannula, ready for placement through the patient's skin. Said cylinder internally includes a spring that can be brought into a loaded condition and, on its upper portion, a trigger that is to release said spring. By depressing the trigger, the spring is released so as to outward project, more particularly through the patient's skin, the needle located in the lower portion of the device. Once the needle is placed through the skin, a slight traction is sufficient to retract the device and leave the needle in place, in the correct position.

[0006] A problem with such kind of devices is that the patient is to provide for the correct introduction of the infusion set into the lower portion of the cylinder, to ensure a correct needle positioning.

[0007] It is a main object of the present invention to provide a container within which the needle and the related cannula are already correctly positioned, so that the patient only has to place said container against his/her skin and to release the needle through a simple movement.

[0008] Another drawback of the known devices is that, while the needle is being placed inside the device, the user risks to prick himself/herself while handling the needle. Moreover, at such step, the needle is exposed to the outside environment and in particular to germs and bacteria.

[0009] Thus, it is another object of the present invention to provide a container for a disposable needle that does not result in the risk for the user to prick himself/herself during use and that allows maintaining hygiene

and safety in respect of possible contamination by external agents.

[0010] The above and other objects of the invention are achieved by a container as defined in the appended claims.

[0011] The container according to the invention has the appearance of a small housing of plastic material, already containing the needle connected with the related cannula and protected from the surrounding environment by means of a protecting film.

[0012] After said film has been removed and the container base has been placed against the skin, a simple push is sufficient to release the needle and pierce the skin.

[0013] Once the needle has been placed through the skin, the container can be removed by slightly pulling it, without risks of displacing the needle from the correct position.

[0014] Advantageously, the construction of a disposable device affords maximum simplicity of use and maximum hygiene.

[0015] A number of embodiments of the invention will be disclosed in greater detail with reference to the accompanying drawings, in which:

- Fig. 1 is a side view of the container according to a first embodiment of the invention, shown before use;
- Fig. 2 is a cross-sectional view taken along line A-A in Fig. 1;
- Fig. 3 is a cross-sectional view taken along line A-A in Fig. 1, after needle insertion;
- Fig. 4 is a cross-sectional view taken along line B-B in Fig. 2;
- Fig. 5 is a cross-sectional view taken along line C-C in Fig. 2;
- Fig. 6 is a top view of the container according to said first embodiment of the invention;
- Fig. 7 is an overall perspective view of the container according to a second embodiment of the invention, shown before use;
- Fig. 8 is an exploded view of the container shown in Fig. 7;
- Fig. 9 is a plan view of the needle-retaining member in the container shown in Fig. 7, shown before assembling;
- Fig. 10 is a side view of the needle-retaining member shown in Fig. 9; and
- Fig. 11 is a cross-sectional view, taken along line D-D, of the needle-retaining member shown in Fig. 9.

[0016] Referring to Fig. 1, the container according to a first embodiment of the present invention comprises a cylindrical housing 1, in which there is defined a cap 1a axially slidable relative to a sleeve 1b when a sufficient pressure is exerted on said cap 1a.

[0017] Said cap 1a moreover has an inner diameter

slightly exceeding the outer diameter of sleeve 1b, so as to allow sleeve 1b to be received within cap 1a when the latter has been wholly depressed.

[0018] Sleeve 1b is integral with a base 1c intended for placing the container against the patient's skin, in the area where the needle is to be inserted.

[0019] A cannula 11, intended to supply the needle located within housing 1 with the drug, as it will be better disclosed hereinafter, radially comes out from sleeve 1b through an axial slit 63.

[0020] Outside housing 1, a removable film 3 is applied onto base 1c, to protect an adhesive gauze 5 placed between said film and base 1c and weakly adhering to base 1c in correspondence of a set of circular portions 7.

[0021] Referring now to Fig. 2, the container according to said first embodiment of the invention comprises, within said housing 1, a retaining member 9 comprising a securing portion 9a directed towards cap 1a and a retaining portion 9b directed towards sleeve 1b.

[0022] Securing portion 9a is firmly held inside an axial cylindrical hub 10 extending within cap 1a and integral therewith. Retaining portion 9b axially extends inside the container and ends, at its end remote from said securing portion 9a, with a plate 13 transversally arranged relative to the axis of retaining member 9.

[0023] As better shown in Fig. 4, said plate 13 has a substantially circular shape and has a pair of diametrically opposite radial grooves 15, through which corresponding axial projections 17 formed within sleeve 1b pass. Said projections are arranged to guide the axial sliding of plate 13, and consequently of member 9, when cap 1a is pressed against sleeve 1b.

[0024] Still with reference to Fig. 4, said plate 13 further comprises a groove 19, diametrically crossing the whole plane of plate 13, perpendicularly to radial grooves 15. Groove 19 retains inlet branch 21a of an L-shaped needle 21 for the infusion of the drug, housed inside the container.

[0025] Turning back to Fig. 2, said groove 19 axially extends inside plate 13 and retaining element 9b and widens, at its end, into a radial hollow 23, thereby to define two diametrically opposite portions of said plate 13. As it will be explained hereinafter, said portions can be deformed to release needle 21 once cap 1a has been depressed.

[0026] Two circumferential rims 25 and 27, respectively, are formed on the internal wall of sleeve 1b to keep plate 13 in engagement against sleeve 1b, thereby preventing cap 1a from sliding until a force sufficient to overcome the resistance of outermost rim 25 relative to said cap 1a is exerted against said cap.

[0027] With reference to Fig. 5, the internal wall of sleeve 1b comprises an axial groove 31 housing outlet branch 21b of L-shaped needle 21.

[0028] Said sleeve 1b further has, at the end of said axial groove 31, a widened portion 41 in correspondence of base 1c, to prevent branch 21b of needle 21

from sticking into the wall of sleeve 1b while advancing towards the outside through opening 37 provided in gauze 5. Cap 1a has a corresponding widening 43 to receive the outer projection defined by said widened portion 41 when sleeve 1b is completely received within cap 1a.

[0029] Turning back to Fig. 2, retaining portion 9b further comprises a pair of diametrically opposite fins 33 upward projecting from plate 13 and diverging towards cap 1a. Said fins 33 end with a convex portion 35, interfering with axial projections 17 when cap 1a is depressed and retaining member 9 is made to slide along sleeve 1b, thereby disengaging plate 13 from rim 25 and bringing the container to the position shown in Fig. 3.

[0030] Referring now to Fig. 3, when cap 1a is completely lowered against sleeve 1b, retaining member 9 is arranged with plate 13 against the inner face of gauze 5, and branch 21b of L-shaped needle 21 will be completely placed through the patient's skin after having passed through opening 37 in gauze 5.

[0031] Referring now to Fig. 6, gauze 5 is joined to a second adhesive gauze 39, which in turn is protected by a respective removable adhesive film. The border of second gauze 39 can be folded on gauze 5 when needle 21 has been inserted and the container has been removed. Thus, the patient can advantageously cover the area of gauze 5 and branch 21a of L-shaped needle 21 by said second gauze 39, whereby only the border of gauze 39 is externally visible and the area occupied by the needle is thus protected.

[0032] The operation of the container according to said first embodiment is as follows: starting from the configuration shown in Fig. 2, protecting film 3 is removed and adhesive gauze 5 is made to adhere to the patient's skin in the area where needle 21 is to be inserted. Pushing cap 1a towards base 1c results, once the resistance of rim 25 has been overcome, in the release of plate 13 and the sliding of cap 1a on sleeve 1b. During this step, needle 21 is placed through the patient's skin and, at the same time, is released from retaining member 9 because of the deformation of plate 13 due to the pressure radially exerted by projections 17 onto fins 33. The container has thus taken the configuration shown in Fig. 3 and it can be removed, while leaving the needle in place thanks to the weak adhesion between base 1c and gauze 5 if compared with the adhesion between gauze 5 and the patient's skin. Subsequently, the protecting film of second gauze 39 can be removed therefrom and gauze 39 can be folded on and made to adhere to gauze 5.

[0033] Referring now to Figs. 7 to 11, a second embodiment of the invention is shown, which differs from the first embodiment in particular in respect of the structure of the needle-retaining member.

[0034] In this second embodiment, the container comprises a cylindrical housing 101, in which a cap 101a and a sleeve 101b are defined. The sleeve has a slightly smaller diameter, so that, when a sufficient pressure is

exerted on cap 101a, the latter is axially slidable relative to sleeve 101b and can internally receive the sleeve. Said sleeve 101b is integral with a base 101c intended for placing the container against the patient's skin.

[0035] Slightly projecting circumferential rims could be provided on the inner surface of the base of cap 101a and on the outer surface of the edge of sleeve 101b remote from base 101c, respectively. Thanks to the co-operation between said circumferential rims, when housing 101 is assembled, said cap 101a is axially slidable on sleeve 101b but it cannot be accidentally separated therefrom.

[0036] Moreover, an annular band, e. g. of plastic material, could be applied around sleeve 101b to prevent cap 101a from accidentally sliding relative to sleeve 101b. Said band can be easily removed by the user before use.

[0037] A cannula 111 radially comes out from sleeve 101b through an axial slit 163. Said cannula is intended to deliver the drug to an L-shaped needle 121, located within housing 101 and comprising an inlet branch 121a, onto which the cannula is fitted, and an outlet branch 121b, intended to be at least partly placed through the patient's skin. Said L-shaped needle 121 is housed within a retaining member 109, contained within housing 101.

[0038] Said retaining member 109 comprises a securing portion 109a and a retaining portion 109b and consists of two coupled half-shells 109c, shaped so as to define therebetween a cavity 161 capable of receiving said needle 121.

[0039] Securing portion 109a comprises two shoulders 157, 159, which are received into corresponding recesses 165, 167 formed in the edge of sleeve 101b remote from base 101c.

[0040] More particularly, recess 165 formed in correspondence with slit 163 is so sized that its edges resiliently press against shoulder 157 of retaining member 109, whereas the opposite recess 167 is oversized with respect to the corresponding shoulder 159 in said member 109, so that a clearance is left.

[0041] In the alternative, a pair of facing resilient members could be formed on the internal surface of said sleeve 101b, which members radially project towards the centre of said sleeve to such an extent that they press against half-shells 109c of said member 109.

[0042] Advantageously, radial projections 166, 168 are provided on the inner surface of sleeve 101b in correspondence with recesses 165, 167 and are firmly held between said shoulders 157, 159 and corresponding teeth 158, 160 formed in securing portion 109a of said retaining member 109. In such manner, retaining member 109 is axially joined to sleeve 101b.

[0043] Furthermore, a recess 155, extending up to cavity 161, is defined in securing portion 109a, to receive a projection 151 centrally provided inside cap 101a. Preferably, end 153 of said projection 151 is so shaped that it conforms to the curved profile of cannula

111.

[0044] Two facing L-shaped axial projections 169, diametrically opposed and parallel to slit 163, are provided inside sleeve 101b and they form a seat for the portion of said retaining member 109 receiving outlet branch 121b of needle 121.

[0045] Figs. 9 to 11 show in detail retaining member 109.

[0046] Advantageously, said retaining member 109 consists of two facing half-shells 109c, whereby positioning of needle 121 is particularly easy: indeed, it will be sufficient to place said needle between said half-shells 109c and then to join them, thereby blocking the needle therebetween. Said half-shells 109c are preferably formed by moulding into a single element, and therefore they are advantageously joined by a flexible member 171 making their assembling easier.

[0047] One of said half-shells 109c comprises three pins 173 engaging corresponding holes 175 in the other half-shell 109c, thereby assisting in correctly aligning both half-shells 109c at the assembling and, subsequently, in keeping them joined.

[0048] Both half-shells 109c have a groove 161a, 161b defining cavity 161 when half-shells 109c are joined.

[0049] Inlet branch 121a of needle 121, on which cannula 111 is fitted, is retained inside cavity 161 thanks to the co-operation between a pair of support projections 177, 178 and a pair of rigid tongues 181 provided on one of half-shells 109c and housed in respective seats 179 in the other half-shell.

[0050] One of said support projections, 178, is suitably arranged on one half-shell 109c in correspondence of the bend between inlet and outlet branches 121a, 121b of needle 121. When the retaining member 109 is assembled, said projection 178 prevents, by cooperating with the surface of the facing half-shell 109, needle removal from housing 101.

[0051] As shown in Fig. 11, retaining portion 109b of each half-shell 109c is divided into two sections 109d, 109e connected by a flexible connecting member 183 allowing limited relative displacements of said sections.

[0052] When half-shells 109c are joined together, sections 109e in the respective half-shells adhere to each other, whereas a passage for outlet branch 121b of needle 121 is defined between sections 109d.

[0053] In this second embodiment, insertion and release of the needle take place as follows. When pushing cap 101a with sufficient force towards container base 101c, projection 151 presses against cannula 111 and, by overcoming the resistance of pins 173 and the elastic resistance of sleeve 101b, said projection forces half-shells 109c apart. Sections 109d of said half-shells 109c cannot be separated, since they are rigidly retained by L-shaped projections of sleeve 101b, so that the passage for outlet branch 121b of needle 121 defined therebetween keeps unchanged. On the contrary, sections 109e of said half-shells can be spaced apart, by over-

coming the elastic resistance of the edges of recess 165 in sleeve 101b. In such manner, cannula 111 can pass through half-shells 109c along slit 163, while needle 121 is guided between facing sections 109d of half-shells 109c, until its outlet branch 121b becomes completely placed through the patient's skin.

[0054] Similarly to what described in connection with the first embodiment of the invention, also in this second embodiment the container can comprise, outside housing 101 and against base 101c, an adhesive gauze 5 weakly adhering to base 101c in correspondence of a set of circular portions. Thus, gauze 5 can remain adhering to the patient's skin after needle 121 has been placed through the patient's skin and the container has been removed. Said adhesive gauze 5 could be possibly joined with a second, protecting adhesive gauze which could be folded onto said first gauze after container removal.

[0055] It is clear that the above description has been given only by way of non-limiting example and that changes and modifications are possible without departing from the scope of the invention.

Claims

1. A container for a disposable needle, intended to facilitate needle placement through a patient's skin, the container comprising:
 - a cylindrical housing (1; 101) in which there are defined a cap (1a; 101a) and a sleeve (1b; 101b) equipped with a resting base (1c; 101c), said cap (1a; 101a) being axially slidable relative to said sleeve (1b; 101b) when a sufficient pressure is exerted on said cap (1a; 101a);
 - a needle (21; 121), located inside said housing so as to be directed towards said resting base (1c; 101c) and equipped with a cannula (11; 111), coming out from said housing (1; 101), for the infusion of the drug through said needle (21; 121);
 - a retaining member (9; 109), which is located within said housing (1; 101) and to which said needle (21; 121) is secured;
 - means for releasing said needle (21; 121) from said retaining member (9; 109) when said cap (1a; 101a) is made to slide on said sleeve (1b; 101b), thereby allowing the placement of said needle under the patient's skin and the subsequent removal of said container.
2. A container as claimed in claim 1, wherein said base (1c; 101c) has, on its outer face, a gauze (5) weakly adhering to said base (1c; 101c) and of which the other face is adhesive and is protected by a removable protection film (3).
3. A container as claimed in claim 2, wherein said gauze (5) is weakly joined to said base in correspondence of a set of circular portions (7).
4. A container as claimed in claim 1, wherein said sleeve (1b; 101b) has an axial slit (63; 163) through which said cannula (11; 111) radially comes out and along which said cannula (11; 111) is slidable when said cap (1a; 101a) is made to slide on said sleeve (1b; 101b).
5. A container as claimed in claim 2, wherein said needle (21; 121) is an L-shaped needle and has a drug inlet branch (21a; 121a) transversally arranged within said housing and an axially arranged drug outlet branch (21a; 121a), said inlet branch being connected to said cannula (11; 111) radially coming out from said container.
6. A container as claimed in claim 5, wherein said retaining member (9) includes a securing portion (9a) directed towards said cap (1a) and a retaining portion (9b) directed towards said sleeve (1b), said securing portion (9a) being firmly held inside an axial cylindrical hub (10) extending within the cap (1a) and integral therewith, and said retaining portion (9b) axially extending within the housing (1) and ending, at its end remote from said securing portion (9a), with a plate (13) transversally arranged relative to the axis of the retaining member (9), said plate (13) being engaged against said sleeve (1b) so as to allow sliding of said cap (1a) on said sleeve (1b) when said plate is released from said sleeve (1b).
7. A container as claimed in claim 6, wherein said plate (13) has a substantially circular shape and comprises a pair of diametrically opposite radial grooves (15) for the passage of corresponding axial projections (17) formed within the sleeve (1b) and arranged to guide the axial sliding of the plate (13), and consequently of the retaining member (9), when said cap (1a) is depressed.
8. A container as claimed in claim 7, wherein said plate (13) comprises a groove (19), diametrically crossing the whole plane of the plate (13) and retaining the inlet branch (21a) of the L-shaped needle (21) for the infusion of the drug, said groove (19) being arranged perpendicularly to said radial grooves (15).
9. A container as claimed in claim 8, wherein said groove (19) retaining the needle (21) axially extends inside the plate (13) and the retaining member (9) and widens at its end, into a radial hollow (23), thereby to define two diametrically opposite portions of said plate (13), which portions can be

- deformed to release the needle (21) retained in said groove (19).
10. A container as claimed in claim 9, wherein a pair of circumferential rims (25, 27) are formed on the internal wall of said sleeve (1b) to keep the plate (13) in engagement with said sleeve (1b), and wherein the internal wall of said sleeve (1b) comprises an axial groove (31) through which the outlet branch (21b) of the L-shaped needle (21) passes.
 11. A container as claimed in claim 10, wherein said means for releasing said needle (21) from said retaining member (9) comprises a pair of diametrically opposite fins (33), which are formed in the retaining portion (9b) of said retaining member and which upward project from the plate (13) and diverge towards the cap (1a), said fins (33) ending with a convex portion (35) interfering with said axial projections (17) when the cap (1a) is depressed and the retaining member (9) is made to slide along the sleeve (1b) thereby releasing the plate (13) from the circumferential rims (25, 27), so that, when the cap (1a) is completely lowered against the sleeve (1b), the retaining member (9) is arranged with the plate (13) against the gauze (5) and the branch (21b) of the L-shaped needle (21) is completely placed through the patient's skin after having passed through the gauze (5) in correspondence of an opening (37) provided therein.
 12. A container as claimed in claim 5, wherein said retaining member (9; 109) consists of two coupled half-shells (109c) and includes a securing portion (109a) directed towards said cap (101a) and a retaining portion (109b) directed towards said sleeve (101b), said retaining portion (109b) including a cavity (161) between said half-shells (109c) for receiving said needle (121), and said securing portion (109a) comprising two shoulders (157, 159), which are received into corresponding recesses (165, 167) formed in the edge of the sleeve (101b) remote from said base (101c), and an axial recess (155) extending up to said cavity (161).
 13. A container as claimed in claim 12, wherein said sleeve (101b) comprises means for resiliently retaining said half-shells (109c) against each other.
 14. A container as claimed in claim 12, wherein respective radial projections (166, 168) are provided on the inner surface of said sleeve (101b) in correspondence with the recesses (165, 167), which projections co-operate with said shoulders (157, 159) and with respective teeth (158, 160) formed in the securing portion (109a) of said retaining member (109) to axially join said retaining member (109) to said sleeve (101b).
 15. A container as claimed in claim 12, wherein one of said half-shells (109c) comprises one or more pins (173) engaging corresponding holes (175) in the other half-shell when said half-shells are coupled to each other.
 16. A container as claimed in claim 12, wherein the inlet branch (121a) of said needle (121) is retained inside said cavity (161) thanks to the co-operation between one or more support projections (177, 178) and one or more tongues (181) provided on one of said half-shells (109c) and received in respective seats (179) provided in the other half-shell.
 17. A container as claimed in claim 16, wherein one of said support projections (178) is arranged in correspondence of the bend between the inlet and outlet branches of said needle (121) and it prevents transversal movements of said needle (121) relative to said sleeve (101b).
 18. A container as claimed in claim 12, wherein the half-shells (109c) are divided, in correspondence of said retaining portion (109b), into first sections (109d) and second sections (109e) connected by a flexible connecting member (183), said first sections (109d) being so shaped that, when said half-shells (109c) are joined to each other, they define therebetween a passage for the outlet branch (121b) of said needle (121).
 19. A container as claimed in claim 18, wherein said sleeve (101b) comprises two facing L-shaped axial projections (169) forming a seat for said first sections (109d).
 20. A container as claimed in claim 19, wherein said means for releasing said needle (121) from said retaining member (109) comprise a projection (151) provided inside said cap (101a) and received within said recess (155), so that, when the cap (101a) is made to slide on the sleeve (101b), said projection (151) forces apart said second sections (109e) of the half-shells (109c) of said retaining member (109) and pushes the inlet branch (121a) of said needle (121) towards the container base (101c), until the complete placement of the outlet branch (121b) of said needle (121) through the patient's skin.
 21. A container as claimed in claim 11 or 20, further comprising a second gauze (39), protected by a respective removable adhesive film and joined with said first gauze (5), the second gauze being foldable on the first gauze (5) when the needle (21; 121) has been inserted and the container (1; 101) has been removed, whereby the first gauze (5) and the inlet branch (21a; 121a) of the needle (21; 121) can

be covered leaving only said second gauze (39) exposed.

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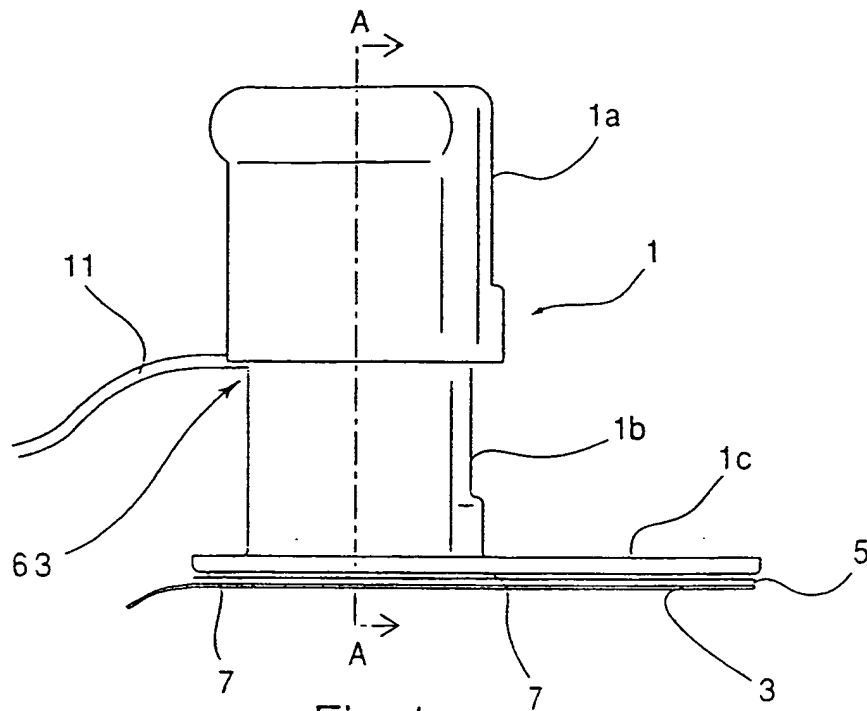


Fig. 1

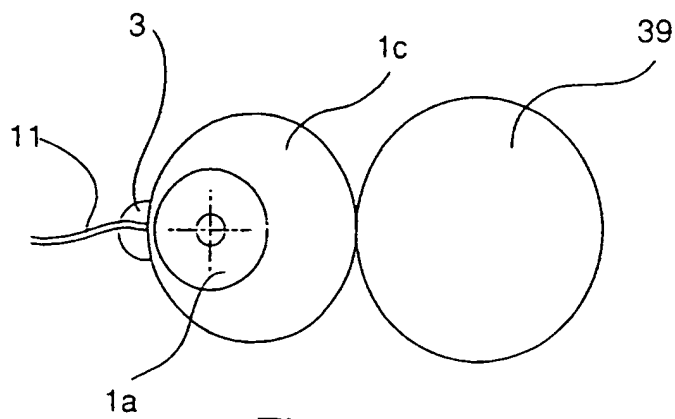


Fig. 6

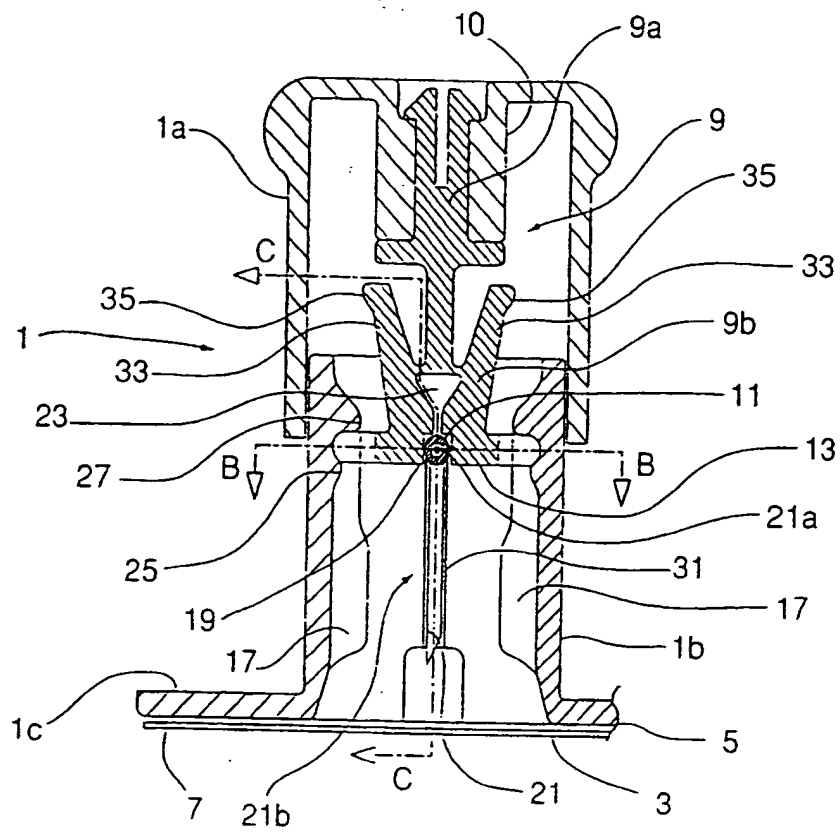


Fig. 2

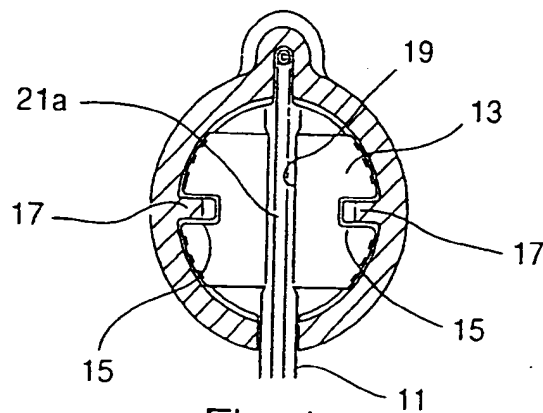


Fig. 4

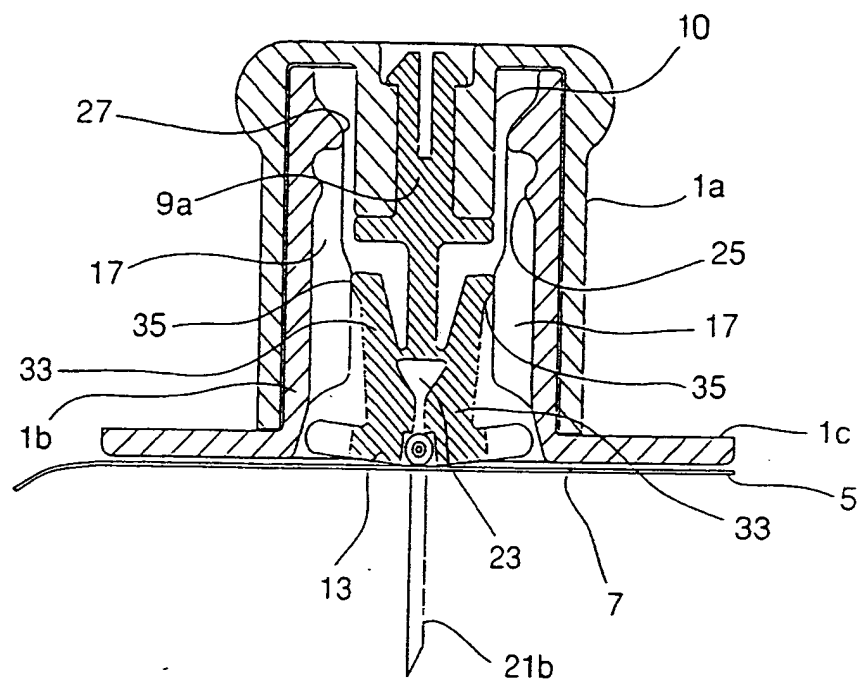


Fig. 3

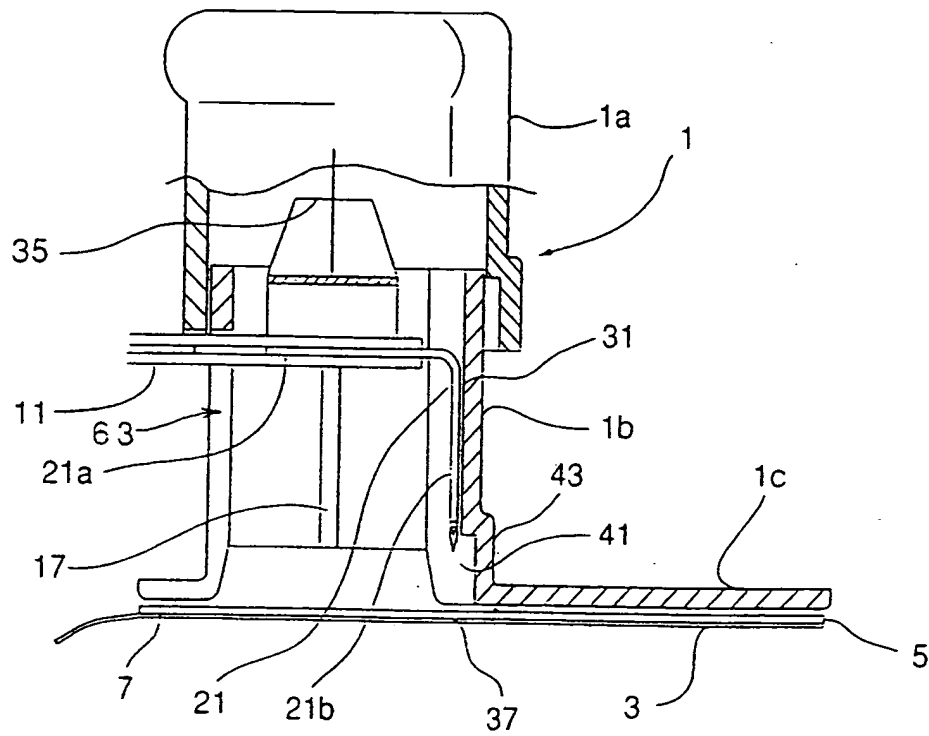


Fig. 5

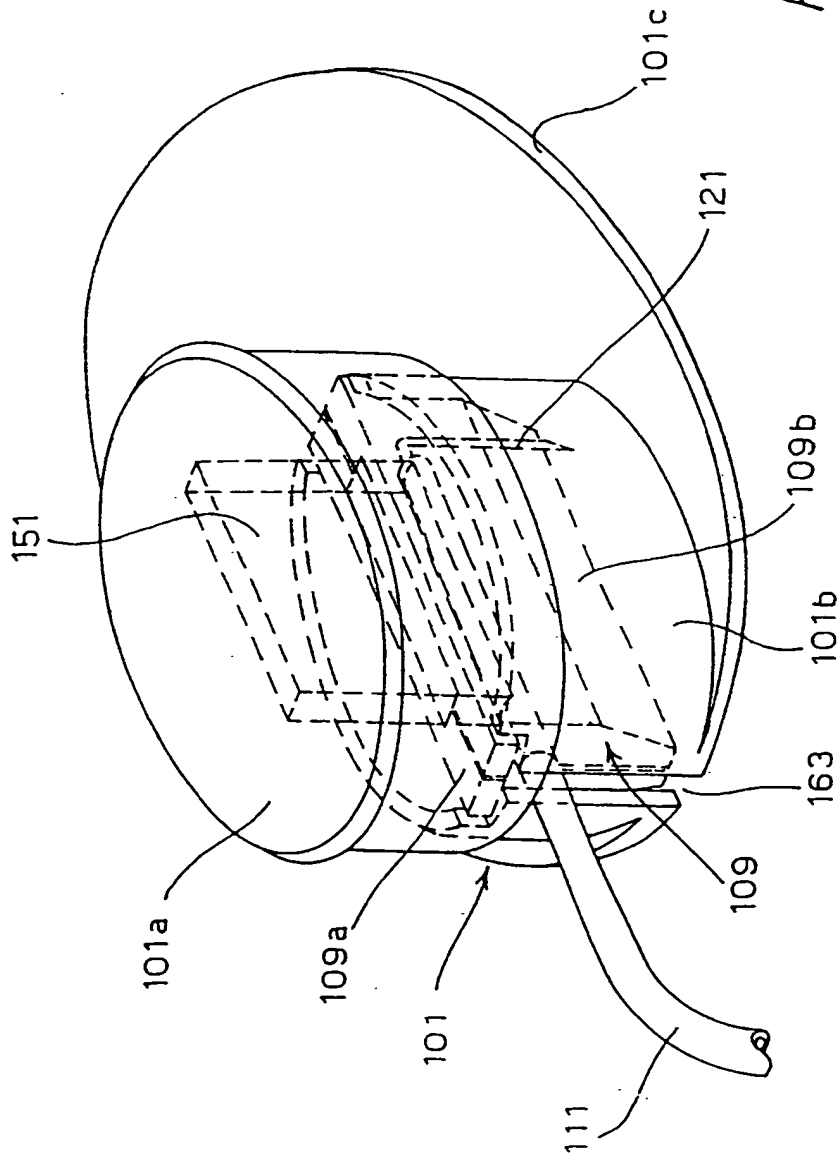
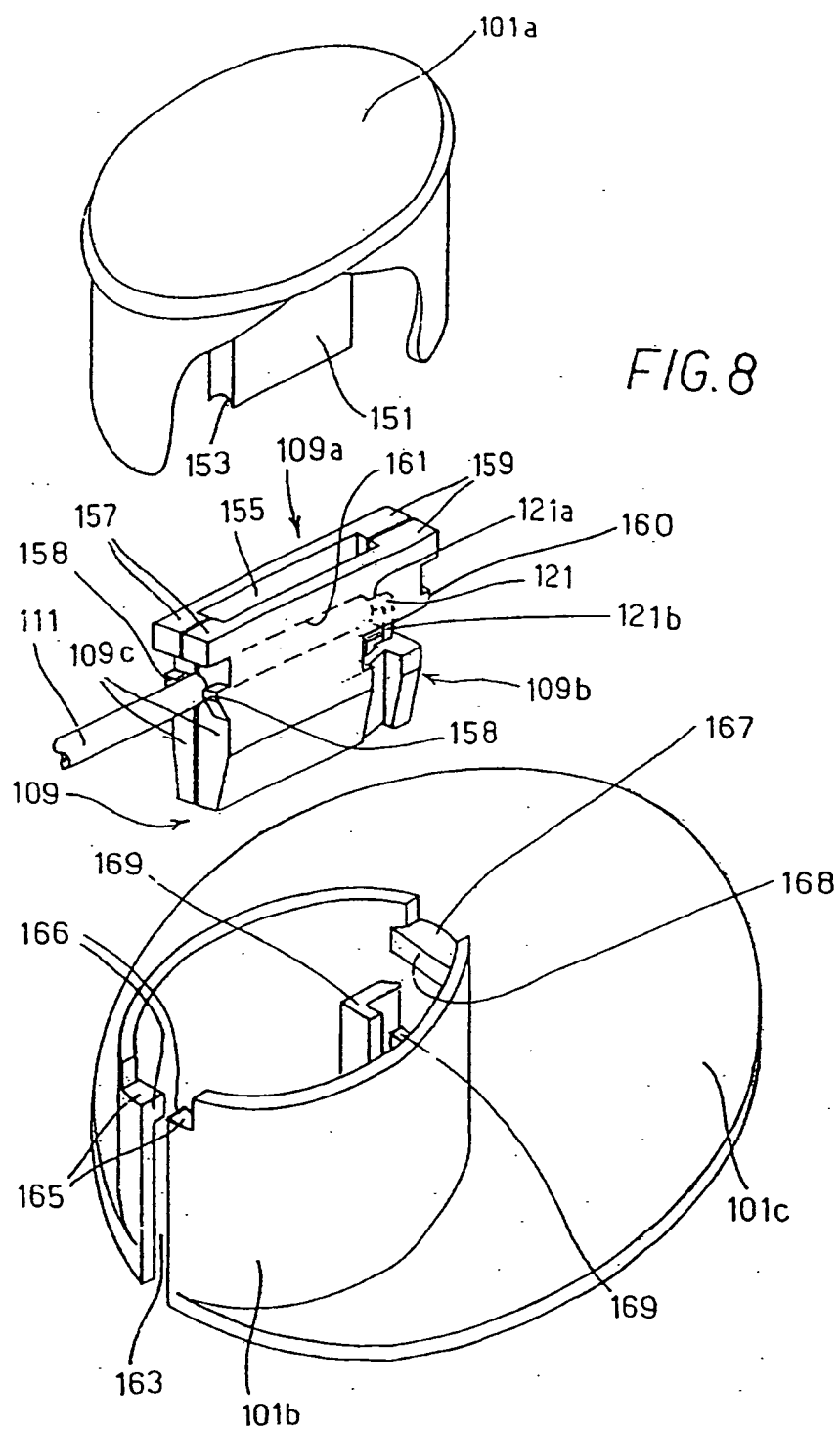


FIG. 7



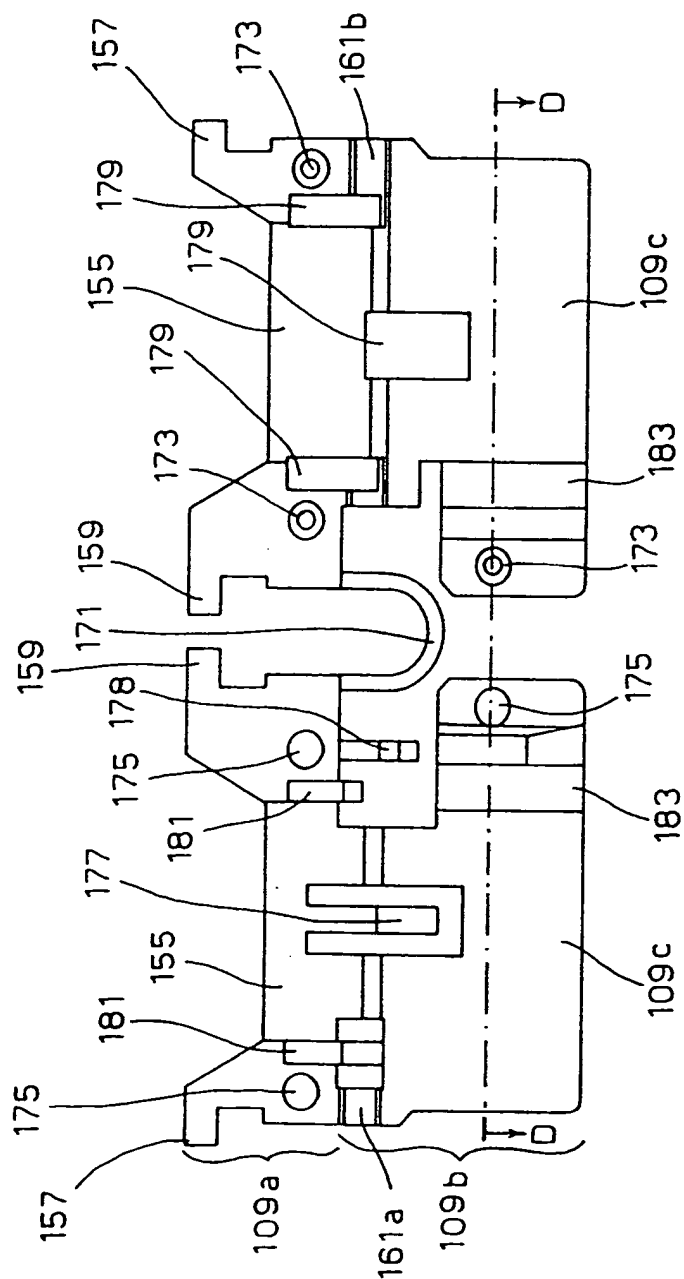
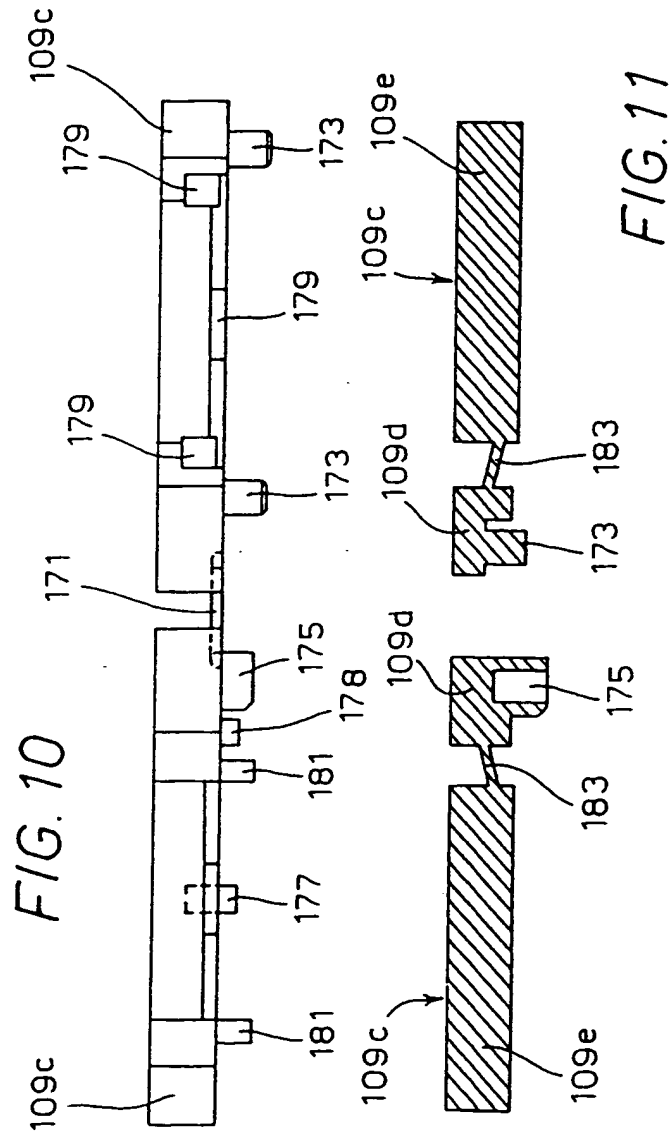


FIG. 9





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 02 8748

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 6 093 172 A (FIELD JEFFREY F ET AL) 25 July 2000 (2000-07-25)	1,4	A61M5/158
A	* the whole document *	2,3,5-21	A61M5/32
A	FR 2 752 164 A (VYGON) 13 February 1998 (1998-02-13) * page 2, line 35 - page 4, line 7; figures 7A,7B *	1-21	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61M
The present search report has been drawn up for all claims			
Place of search MUNICH		Date of completion of the search 8 April 2003	Examiner Ceccarelli, D
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